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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/459,141	06/02/95	BERMAN	P P0233C6

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EXAMINER	
NELSON, B	
ART UNIT	**PAPER NUMBER**
1648	31
DATE MAILED:	09/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/459,141	Applicant(s) Phillip Berman
	Examiner Brett Nelson	Group Art Unit 1648

☒ Responsive to communication(s) filed on *Aug. 10, 2000* .

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-15* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) *2, 6-8, 14, and 15* is/are allowed.

☒ Claim(s) *1, 3-5, and 9-13* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

3. The examiner acknowledges receipt of the amendment filed Aug. 10, 2000 amending claim 9. Claims 1-15 are pending and under consideration.

Applicant's arguments filed Aug. 10, 2000 have been fully considered but they are not persuasive.

4. The rejection of claims 1, 3-5 and 9-13 under 35 U.S.C. 112, first paragraph, is maintained for reasons of record.

The rejection stated that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a vaccine and a method of making a vaccine against any pathogen or to a method of immunizing a patient against herpes by administering a truncated, membrane free derivative of a membrane bound polypeptide. The broadest claim encompasses all viral, bacterial, fungal and protozoan species. The specification lacks sufficient guidance and teaching to enable entire scope of the claims. Moreover, the specification does not contain sufficient guidance or teaching to enable a vaccine against herpes by administering a truncated, membrane free derivative of a membrane bound polypeptide other than glycoprotein D. The

specification states on page 46 that the function of the glycoproteins C and F are unknown and that it is not clear that gC and gF are indispensable to the viruses during in vivo infection of the human and the establishment of latency. While the specification describes sequence homologies between gC and gF, the specification lacks enablement to show a correlation between gC, gF or other herpes glycoproteins and gD, such that one might reasonably expect similarity in structure and function. Thus it would appear that the role of the gC, gF or other glycoproteins in generating protective immune responses has also not been clearly defined and one would not be able to reasonably predict success with a vaccine against herpes simplex virus comprising glycoproteins other than glycoprotein D absence evidence of its function.

While the specification contains examples showing administering glycoprotein D to mice, the specification does not contain any teaching or guidance which shows that the results obtained with glycoprotein D correlate to other herpes glycoproteins. Moreover, Mester et al. (Rev. Inf. Dis. 1991) state that misleading results can be obtained from the mouse used as a model to identify proteins or peptides that are presumed to be important for inducing immunity to HSV.

In view of all of the above, it is determined that the specification is not commensurate in scope with the invention as claimed.

Applicant mainly urges that surface antigens from herpes and other viruses were known at the time of filing, Ghiasi et al. show that other herpes proteins were immunogenic and that a combination or herpes proteins were protective against HSV induced eye disease, the specification discloses other herpes glycoproteins and that one of skill in the art appreciates that a protein that is capable of raising antibodies is immunogenic, Bernstein et al. describe different HSV other vaccines, Peng et al. disclose immunizing with GD or Ght-gl, Nesburn et al. disclose that gD was used to protect against HSV, the Rose declaration shows that one of skill in the art would expect truncated glycoproteins to be effective for vaccination against herpes, and the Secher declaration states that the scientific strength of the instant invention is that it involves a glycoprotein and not the whole virus.

It should be noted that the claims are not drawn to immunogenic compositions, but recite vaccines. While applicant urges that one of skill in the art would expect the glycoproteins to be immunogenic, the claims are drawn to vaccines and methods of producing vaccines. One of skill in the art would not expect the data which involve glycoprotein gD to extrapolate any pathogens (including parasites, bacteria, etc) other than Herpes 1 or 2 nor would they expect the data to

extrapolate to all glycoproteins. The broadest claim appears to encompass a vaccine against HIV. It is well known that HIV vaccines have been ineffective. The specification states on page 46 that the function of the glycoproteins C and F are unknown and that it is not clear that gC and gF are indispensable to the viruses during in vivo infection of the human and the establishment of latency. While the specification describes sequence homologies between gC and gF, the specification lacks enablement to show a correlation between gC, gF or other herpes glycoproteins and gD, such that one might reasonably expect similarity in structure and function. Thus it would appear that the role of the gC, gF or other glycoproteins in generating protective immune responses has also not been clearly defined and one would not be able to reasonably predict success with a vaccine against herpes simplex virus comprising glycoproteins other than glycoprotein D absence evidence of its function. Furthermore, while the specification contains examples showing administering glycoprotein D to mice, the specification does not contain any teaching or guidance which shows that the results obtained with glycoprotein D correlate to other herpes glycoproteins. Additionally, the references cited by applicant all contain *in vitro*, mouse, and/or rabbit data and are not commensurate in scope with the claimed invention. Moreover, Mester et al. (Rev. Inf. Dis. 1991) state that misleading results can be obtained from the mouse used as a model to identify proteins or peptides that are presumed to be important for inducing immunity to HSV. This appears to be corroborated by the Rose declaration in that Dr. Rose states "one of ordinary skill in the art could not have predicted that a successful vaccine that raises neutralizing antibodies could have been produced based essentially on a truncated, membrane free derivative of a membrane-bound

glycoprotein of the virus". Therefore, it appears one of skill in the art would not have expected the data which appears to show protection from herpes 1 or 2 employing glycoprotein D to correlate to protection from other pathogens, including herpes virus, employing other glycoproteins. Nor would one of skill in the art expect *in vitro*, mouse, and/or rabbit data to correlate to humans. The Secher declaration states that an animal needs to be protected from disease in order to support the terminology "vaccine". There is nothing of record which shows that any other glycoproteins were protective or that animals were protected from any disease other than Herpes 1 or 2. Therefore, the rejection is maintained.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brett Nelson, Art Unit 1648 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the

examiner without entry. The Art Unit 1648 FAX telephone number is (703)308-4426. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Brett Nelson whose telephone number is (703) 306-3219.

If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner James C. Housel whose telephone number is (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

NELSON/bn
September 7, 2000

Jeffrey Stucker
JEFFREY STUCKER
PRIMARY EXAMINER